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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,702	05/04/2000	TAKASHI GOTO	2000-0578A	3474

7590 12/19/2001  
WENDROTH LIND & PONACK  
2033 K STREET NW  
SUITE 800  
WASHINGTON, DC 20006

EXAMINER
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TAYLOR, JANELLE E

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/530,702

Applicant(s)

GOTO ET AL.

Examiner

Janell Taylor Cleveland

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 18-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1655

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 18-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5. The groups remain restricted, however, because group I lacks a special technical feature which would distinguish it from the prior art. Group II is considered a distinct group because it is a production method, which method is not required to obtain the product of group I.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffith et al. (Journal of Biological Chemistry, Vol. 260, No. 4, pp. 2218-2225, 1985, made of record in the IDS submitted 8-30-01).

Claim 12 is drawn to a heparin cofactor II (HCII)-containing preparation free of a degrading factor. Claim 13 is drawn to a HCII containing preparation substantially free of a degrading factor and degraded HCII. Claim 14 is drawn to an HCII-containing preparation substantially free of a degrading factor, wherein the HCII has a purity of not less than 98%. Claim 15 is drawn to the HCII of claim 12, which is free of infective

Art Unit: 1655

virus. Claim 16 is drawn to the HCII containing preparation of claim 13, which is substantially free of an infective virus. Claim 17 is drawn to the HCII preparation of claim 14, which is free of an infective virus.

Griffith et al. teaches "Heparin cofactor II was purified 1800 fold from human plasma to further characterize the structural and functional properties of the protein." (Abstract.) Griffith also teaches that a "partially degraded form of heparin cofactor II was obtained..." (Abstract). Since Griffith teaches that the HCII and the partially degraded HCII were separated, and in fact compared to each other in an assay, the purified HCII must have been free of the degraded HCII, as well as the degrading factor. Also, since the HCII was purified, it would have also been free of an infective virus as well. Therefore, Griffith anticipates all of the limitations of claims 12-17

### ***Summary***

Claims 12-17 are rejected under 35 U.S.C. 102(b). No claims are free of the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Art Unit: 1655

Papers related to this application may be submitted by facsimile transmission.

Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

December 17, 2001



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600